

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VENTANA MEDICAL SYSTEMS, INC.,

Plaintiff,

v.

DAKOCYTOMATION CALIFORNIA INC.,

Defendant.

C.A. No. 04-1522-GMS

**DEFENDANT DAKOCYTOMATION CALIFORNIA INC.'S MARKMAN BRIEF**

Dated: October 17, 2005

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## **I. INTRODUCTION**

The defendant, DakoCytomation California Inc. (“DakoCytomation”), hereby submits its “Markman” brief<sup>1</sup> relating to the construction of the key claim limitations of the plaintiff’s, Ventana Medical Systems Inc.’s (“Ventana”), patent-in-suit, Copeland et al., U.S. Patent No. 6,827,901 B2 (“the ‘901 patent”) (Ex. A).<sup>2</sup> The ‘901 patent generally relates to a laboratory instrument that automatically stains tissue samples on glass microscope slides.

Ventana contends that DakoCytomation’s Artisan™ instrument infringes claims 1-9, 20-22, 24-25, 30 and 45 of the ‘901 patent. Of these asserted claims, only claims 1 and 45 are independent. Both independent claims, and thus all the asserted claims, are limited by the claim terms addressed in this memorandum. The terms all concern how and where the patented invention mixes chemicals, called reagents, that stain the tissue samples.

### **A. Reagent Mixing in the ‘901 Patent**

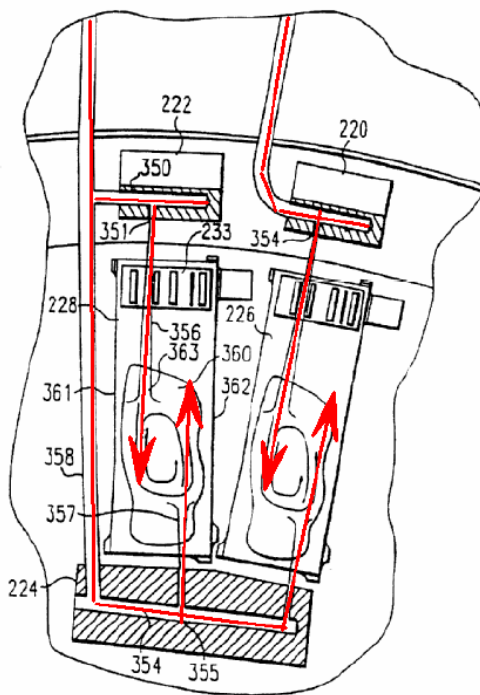
The ‘901 patent describes an instrument that automatically stains tissue samples, so that physicians can highlight and view portions of the tissue. Staining is helpful to the diagnosis of diseases, such as cancer. It involves exposing the samples to a sequence of chemicals under controlled conditions. Historically, staining was done manually. Over approximately the past twenty years, many companies, including the parties to this case, have developed instruments that automate staining. These instruments are faster and more efficient than manual staining methods. A key aspect of automated tissue staining involves adding and mixing the appropriate chemicals at the right time and under proper conditions. These chemicals are generically referred to as reagents.

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<sup>1</sup> *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996).

<sup>2</sup> The Exhibits referenced herein are attached to the Declaration of Timothy Devlin.

Mixing reagents on slides creates unique problems, as compared to mixing reagents in other medium, such as test tubes. In fact, the inventors of the '901 patent told the United States Patent and Trademark Office ("PTO"), "agitating liquids on slides pose difficult and unexpected agitation problems." (Ex. B at 16.) Slides are flat, which means, as the inventors explained, "[s]lides do not have a receptacle to hold liquids." Thus, reagents can easily spill off of the slide's surface. *Id.* ("[A]n air stream could likely direct some or all of the liquid off of the slide.") The '901 patent purports to solve this problem by using conical streams of air called "air jets" to swirl the reagents in a circle within a discrete area, such that they do not spill off of the surface of the slide. The '901 patent discloses two mixing embodiments. They are similar in all respects, except the number of air jets used to spin the reagents. The first embodiment is depicted below.



(Ex. A, Fig. 17.) The red arrows indicate air flow. The shape and direction of the flow creates air jets that blow past either side of the reagent puddle that sits on the slide. Since the jets are flowing in opposite directions, they cause the reagents to spin in a vortex.

This patent describes this first embodiment as follows:

Pressurized air is supplied to the nozzle channels 350 and 354 by channel 358. The reagent solution covered by a layer 360 of evaporation inhibiting liquid 360 is stirred on the surface of the biological sample by applying at least one gas stream 356 or 357 to an area of the surface of the evaporation inhibiting liquid layer 360 between the center of the evaporation inhibiting liquid and the edge of the planar support surface 361 or 362 of the slide 228. The gas stream impacts the surface of the evaporation liquid surface layer 360 and moves the underlying reagent solution in a circular path on the tissue section.

Col. 12, line 58 – Col. 13, line 2. A second embodiment, employing only one air jet is also disclosed. As depicted below, the single jet, depicted in red also mixes the reagents while keeping them on the slide.

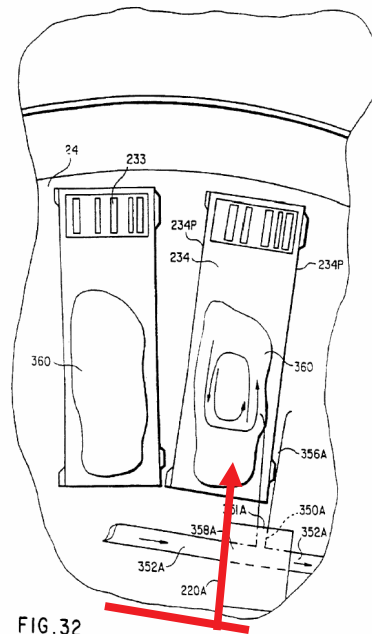


FIG. 32

(Ex. A, Fig. 32.) As the patent explains:

FIG. 32 illustrates an alternative embodiment of a vortex air mixer 220A which in this case is a single mixer. Each of the single vortex air mixers 220A is positioned at the inner radius of the slides 234 such that an [sic] gas jet or cone 356A of, for example, air or the like, blows outwardly adjacent one of the longitudinal lateral edges 234P of the associated slide 234 to effect mixing in a manner similar to that described with respect to FIG. 17. More specifically, the gas stream 356A impacts the surface of the evaporation liquid surface layer 360 and moves the underlying reagent solution in a circular path on the tissue section.

Col. 23, lines 19-29. Swirling of the reagents is the only method of mixing disclosed in the patent. Indeed, it is the key to overcoming the “difficult and unexpected agitation

problems” associated with “agitating liquids on slides” because it keeps the reagents from spilling. (Ex. B at 16.)

The ‘901 patent claims several aspects of this method of mixing. These include the “**reagent agitation zone**,” where mixing occurs, an “**air jet**,” which is the cone of air that blows and swirls the reagents, and “**an air supply means positioned adjacent to a [sic] said reagent agitation zone for mixing reagents**,” which are the structures, next to the slide, that direct the air to mix the reagents. These are the claim limitations that require construction in this case. They are common to all of the asserted claims. Claim 1 is representative:

1. A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:
  - a reagent carousel having a plurality of reagent container supports thereon;
  - a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;
  - a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto the slide;
  - a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide having a substantially planar support surface, said slide having a **reagent agitation zone** for adding and mixing reagents thereto located on the slide’s upper surface; and
  - an air mixer comprising **an air jet** and an **air supply means positioned adjacent to a said reagent agitation zone for mixing reagents**, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

This memorandum concerns the construction of these highlighted terms.



## II. ARGUMENT

### A. Claim Construction Law

Claim construction is a question of law, and it is primarily accomplished by a review of the patent itself, i.e. the claims and the specification, as well as the file history and cited references. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Collectively these sources are referred to as the “intrinsic record”. *Vitronics Corp., v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Extrinsic evidence such as expert testimony, may also be considered as an inherent part of claim construction, but usually only for background or confirmatory purposes. *Tanabe Seiyaku Co. Ltd. v. U.S. Int’l Trade Comm’n.*, 109 F.3d 726, 732 (Fed. Cir. 1997). Very recently, an *en banc* panel of the Federal Circuit clarified the approach that should be taken with respect to the claim construction analysis. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

The Court should begin by examining the language of the claims themselves. These words should be accorded their plain and ordinary meaning, as measured by one of ordinary skill in the art of the invention. *Id.* at 1312-13. As the *Phillips* case explains, “[t]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.” *Id.* at 1313. While the claims are the starting point, they are seldom the end point. The written description is highly relevant. Indeed, the *Phillips* court concluded:

As we stated in *Vitronics*, the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’

*Id.* at 1316 (quoting *Vitronics*, 90 F.3d at 1582.) The specification is especially relevant to so called means-plus-function claims. These claims must be construed in view of the written description. *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1551 (Fed. Cir. 1997); see also *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1321 (Fed. Cir. 2003). Regardless of whether a claim is means-plus-function, however, the Federal

Circuit made clear in the *Phillips* case that the written description is critically important to claim construction. *Phillips*, 415 F.3d at 1316 (“The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in ‘full, clear, concise and exact terms.’”) (quoting 35 U.S.C. § 112, ¶ 1).

Next, the Court may consider the prosecution history of the patent, including the prior art cited therein. *Phillips*, 415 F.3d at 1317 (“The prosecution history, which we have designated as part of the ‘intrinsic evidence,’ consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.”) While perhaps not as probative of claim scope as the written description, “the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Phillips*, 415 F.3d at 1317. It is therefore an important part of claim construction.

Lastly, extrinsic evidence, such as dictionaries, texts and expert testimony may be used to provide background information, or to help understand the intrinsic record. *Id.*

## **B. Construction of Disputed Terms**

For each of the following contested claim terms, DakoCytomation presents its proposed construction and its analysis. The analysis follows the canons of claim construction - namely it examines the claim language itself, the written description, and the file history, including cited references, where appropriate. DakoCytomation does not rely on extrinsic evidence, and the parties appear to agree that none is necessary or appropriate for this case.

### **i. “Reagent Agitation Zone”**

DakoCytomation’s Proposed Construction:

***A region where the apparatus adds and mixes reagents without spilling them.***

***The region is not a “reagent agitation zone” if it has structural boundaries that retain reagents, such as the walls of a receptacle.***

This limitation concerns where reagents are added and mixed. Looking only at the plain language of the this limitation, one might assume that the “reagent agitation zone” is the zone wherein reagents are agitated. However, the written description suggests otherwise. In fact, the text and figures of the patent begin to cast doubt on such a broad construction.

The patent discloses a discrete region on or above the slide where reagents are deposited, and remain without spilling, even during mixing. It provides:

***In another aspect of this invention, the reagent solution is stirred on the surface of the biological sample by applying at least one gas stream to an area of the surface of the evaporation inhibiting liquid layer between the center of the evaporation inhibiting layer and the edge of the planar support surface...***

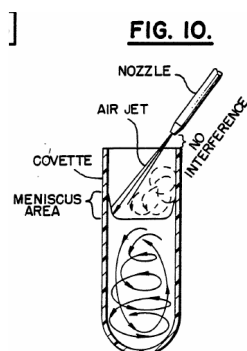
(Col. 4, lines 47-52, emphasis added). This suggests that the zone is defined by the space where the reagents twirl in a vortex while remaining on the slide. The patent then describes two such embodiments – one with a single gas stream and another with two opposing gas streams. (Col 4, lines 52-61). As shown in Figures 17 and 32, and discussed above, both embodiments mix the reagents in by stirring them in this localized region. Importantly, the stirring action in this region is not described as an embodiment. Instead is called an aspect ***of the invention***. This is not simply rhetoric. It shows that the inventors considered this stirring action part of the invention itself and not just an example. Under these circumstances the claims must be so limited. *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1369 (Fed. Cir. 2003). Thus, the written description show that the “reagent agitation zone” is more narrow than simply any place where reagents are mixed.

Next we turn to the file history, which in this case is particularly instructive. It shows that the inventors of the ‘901 patent limited “reagent agitation zone” such that it

cannot include an area within a receptacle. Indeed, the inventors had to do so, because the prior art would not permit a broader scope.

During prosecution the examiner repeatedly rejected the inventors' claims as obvious in view of several prior art referenced. The Ventana inventors overcame these rejections only by convincing the examiner that these references were different from and did not render obvious the claims of the invention. One of the key distinctions that Ventana articulated was that these references do not disclose "a slide having a reagent agitation zone." Instead these references mix reagents inside of container or a receptacle, something different from a slide having a reagent agitation zone.

The main reference, (Ex. C), concerns the mixing of reagents with an air jet aimed inside of a container called a cuvette. This is illustrated below:



Ventana claimed that "[t]he prior art does not disclose or suggest a 'slide having a reagent agitation zone'" and explained:

Hulette discloses using an air jet to agitate the contents of a cuvette. A cuvette is a container with an open end that is partially filled with a liquid. Air is supplied directed into the container to agitate the liquid contents of the cuvette. Importantly, the cuvettes of Hulette, et al are not completely full. This means that there is little or no concern about the air jet expelling fluid from [sic] the container.

It would not be obvious to use the air jet of Hulette to agitate liquids located on the slide because agitating liquids on slides pose difficult and unexpected agitation problems. Slides do not have a receptacle to hold liquids. Therefore, liquids remain on a slide primarily by virtue of (1) the association of the liquid with a solid biological sample; and (2) by its surface tension. One of ordinary skill in the art at the time of the

Applicant's invention would understand, based upon the cited references, that applying air to a [sic] mix a liquid located on the slide would not be an obvious task since an air stream could likely direct some or all of the liquid off of the slide.

(Ex. B at 16-17.) In this argument, Ventana presented several reasons why the prior art did not disclose a reagent agitation zone. The prior art disclosed "containers." The containers are only "partially filled" with liquids. And jets agitate reagents in the containers without "expelling" them. By contrast, a slide having a reagent agitation zone is different because there is no "receptacle" and mixing must be accomplished without directing "some or all of the liquid off of the slide".

In short, Ventana convinced the examiner that the prior art was different did not render its invention obvious, because that prior art mixed reagents within a receptacle or container. The walls of the containers keep the reagents from spilling. Therefore, the Court should interpret the term "reagent agitation zone" as limited to a region without walls where reagents are agitated without spilling.

At first impression it might appear that Ventana distinguished Hulette simply because it discloses cuvettes and not slides. However, the examiner rejected that very assertion.

In a first office action, the examiner rejected all claims as obvious in view of Hulette, et al. (Ex. D at 3-5.) In response, Ventana argued, "Hulette or Kelln et al. are both directed to analysis systems that use cuvettes. In contrast, the claimed invention is directed to analysis systems that use slides." (Ex. E at 12.) The examiner found this distinction, "not persuasive" and explained, "the Office has addressed the issue of slides by citing the prior art of Kamensky, et al." (Ex. F at 2.) Not deterred, Ventana responded to next office action by arguing, "slides and cuvettes are not interchangeable, they each have their own unique uses". (Ex. B at 11.) Again, the examiner was not persuaded. Instead, he clearly stated in his reasons for allowing the claims that the prior art did not disclose a "slide having a reagent agitation zone." (Ex. G at 2.) Thus, the issue was thoroughly debated. The inventors repeatedly argued that their claims were

allowable because Hulette did not disclose slides, and the examiner repeatedly rejected this argument. Instead, the examiner accepted Ventana's argument that the reagent agitation zone was not presented in the prior art. There is no doubt about this, because the examiner explained his reasons for allowing the claims:

[T]he cited prior art fails to teach the claimed combination of a sample carousel arranged beneath a reagent carousel and the *slide having a reagent agitation* zone as claimed in [the pending claims].

(*Id.*). Thus, the basic distinction between cuvettes and slides did not distinguish this invention from the prior art. But, the reagent agitation zone did.

Ventana's proposed construction of "reagent agitation zone" is any space where reagents are added and mixed. This proposed construction ignores the concessions that the Ventana inventors made to get their claims allowed, which is improper. In fact, the primary purpose of consulting the file history during claim construction is to determine "whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). This is precisely what the Ventana inventors did to get their claims allowed.

Moreover, if the Court ignored the inventors' limiting arguments, the examiner's reasons for allowance would no longer apply. As such, the claims would be invalid over the prior art, for the reasons the examiner explained. Such a construction is disfavored. In fact, when more than one possible interpretation exists, claims should be construed as valid, where possible. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 749 (Fed. Cir. 1987).

Accordingly, "reagent agitation zone" should be construed as a region where reagents are added and mixed without spilling, and cannot include a region with structural boundaries that retain reagents, such as the walls of a receptacle.

## ii. "Air Jet"

DakoCytomation's Proposed Construction:

***A conical or cylindrical stream of air.***

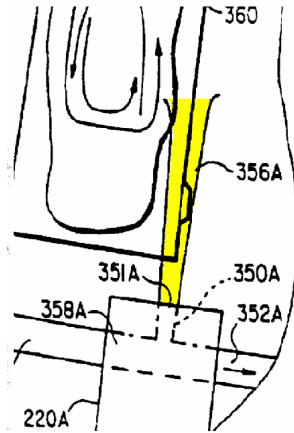
The words “air jet” connote a stream of air blowing in a particular shape – namely a cone or cylinder. The written description, file history and cited art all confirm this definition.

The term “jet” is a familiar one. We encounter jets in our daily routines. Whether it is the jet in a whirlpool, or the jet from a jet ski or jet boat, the stream – of air or water - exits a circular hole in the shape of a cone or cylinder. This is what focuses the stream. Contrast this with the air flow from a ceiling fan or heating duct, or a windshield defroster where the shape is not so confined. Perhaps the clearest comparison is an airplane jet engine versus an airplane propeller engine. Each produces air flow, but common sense and experience tell us that there are important and apparent differences. One key difference is that the jet engine produces air flow in the shape of a cone or cylinder while the propellers do not. This common sense and experience should inform claim construction. As the Federal Circuit instructed in the *Phillips* case:

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.

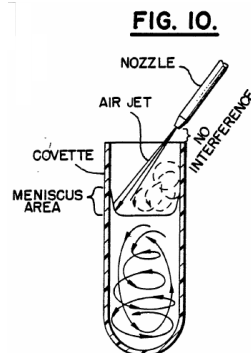
*Phillips*, 415 F.3d at 1314. The widely accepted meaning of air jet is a flow of air in the shape of a cone or cylinder. This plain meaning is confirmed by the patent’s written description.

There are two embodiments in the ‘901 patent that show air jets. Again they appear in figures 17 and 32. In both, the shape of the air stream is a cone. For example, a portion of figure 32 is reproduced below. The air flow is highlighted in yellow:

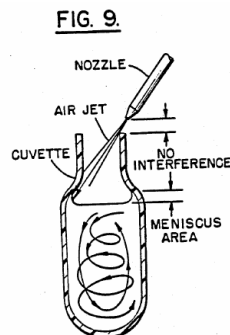


The text of the patent refers to number 356A as a “gas jet or cone” (Col. 23, line 22), indicating that a jet *is* a cone of air.

The file history and cited references lend further support to this construction. The inventors referred to “the ‘air jet’ of Hulette”. Indeed Hulette used the same language. Both were referring to the conical flow of air, as depicted below:



Likewise, the examiner and the applicant made reference to the “air jet” of U.S. Patent No. 4,815,978 (Ex. H). It is reproduced below.





Note that the shape disclosed is the same in the prior art and in the '901 patent. In short, throughout the intrinsic record "air jet" refers to a stream of conical or cylindrical air. This is consistent with the plain meaning of the term. Accordingly, "air jet" should be construed as a stream of conical or cylindrical air and should therefore be rejected.

**iii. "Air supply means positioned adjacent to a [sic] said reagent agitation zone for mixing reagents"**

DakoCytomation's Proposed Construction:

*This is a means-plus-function limitation. The recited function is mixing reagents. The corresponding structure includes the air supply channels 350, 354 and 358 or alternatively air supply channels 350A, 352A and 358A;; vortex mixer air jet blocks 220, 222 and 224 or alternatively the vortex air mixer 220A; nozzles 351 and 355 with central axes which form angles 'd' and 'e' from 5 to 15° with the horizontal or alternatively nozzles 351A with a central axis which forming angles from 5 to 15° with the horizontal.*

The parties agree that this is a means-plus-function limitation. (Ex. I.)

Accordingly, the claim scope is defined by the recited function and the corresponding structure. *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed.Cir. 1999). The parties disagree about both the recited function and the corresponding structure.

**C. Function**

Ventana proposes that the function is to supply air. DakoCytomation agrees that a component of this limitation includes supplying air, but the purpose – as articulated in the claim – is to mix reagents. The difference between the parties' interpretation focuses on whether the phrase "for mixing reagents" modifies "air supply means" or "air mixer". A close look at the claim language itself, and the file history shows that it is the former.

First, in this claim limitation "positioned adjacent to said reagent agitation zone for mixing reagents" directly follows "air supply means." Since modifiers apply to language that immediately follow them, one would expect that "for mixing reagents" modifies "air supply means." This interpretation finds support in the file history.

As originally drafted, the claims referred to an “air mixer positioned adjacent a [sic] agitation zone for mixing reagents when in the air agitation zone.” (Ex. J at 2.) The examiner rejected this claim pursuant to 35 U.S.C. § 112, ¶ 2, which means the examiner concluded that the claims were indefinite. Claims are indefinite when someone of ordinary skill cannot determine their boundaries. *Oakley, Inc. v. Sunglass Hut International*, 316 F.3d 1331, 1340 (Fed. Cir. 2003). The examiner specifically determined that these claims were ambiguous and were missing elements, including a nozzle. (Ex. D at 2.)

In response to this rejection, the Ventana inventors amended the claim, but rather than claim a “nozzle,” they used means-plus-function language:

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents ~~when in the air agitation zone~~, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

(Ex. E at 2.) Moreover, the Ventana inventors placed the “air supply means” next to “positioned adjacent to” and “for mixing reagents” to clarify that the location and function of the means clause. After making these changes, the inventors told the examiner, “The Examiner’s rejection [of the relevant claims] has been overcome by amending claim 72 to recite the essential elements identified by the Examiner.” (*Id.* at 11.) Note that the Examiner invited the inventors to claim a “nozzle.” Instead, they separately claimed an *air jet* and an *air supply means positioned adjacent to said reagent agitation zone for mixing reagents*. This change in the claim overcame the indefiniteness rejection. Thus, by indicating that the air supply means is for mixing reagents, the inventors successfully received claims.

By contrast, Ventana’s proposed interpretation does not make sense. If “positioned adjacent to said reagent agitation zone for mixing reagents” modifies “air mixer” then the inventors would not have later referred to “said air mixer.” They could

have drafted the claim to say "...positioned adjacent to said reagent agitation zone for mixing reagents, and directing a jet of air at the reagent agitation zone..." and left out "said air mixer" completely, or they could have placed "said air mixer" before "positioned adjacent to" and "directing a jet of air..." This language would have made clear that everything from "positioned adjacent to..." modifies "air mixer." But because the claim instead places "said air mixer" after "for mixing reagents" the claim means that "for mixing reagents" modifies "air supply means" rather than "air mixer."

To make the claim read as Ventana now interprets it, one would have to change the language as follows:

An air mixer comprising an air jet and an air supply means, said air mixer positioned adjacent to said reagent agitation zone for mixing reagents.

Having not included that language in the claims, Ventana cannot now pencil it in.

*Autogiro Co. of America v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967).

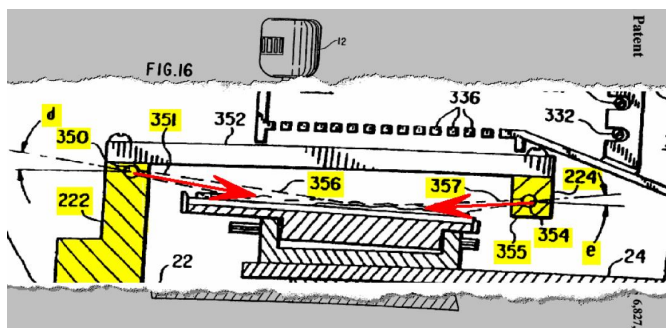
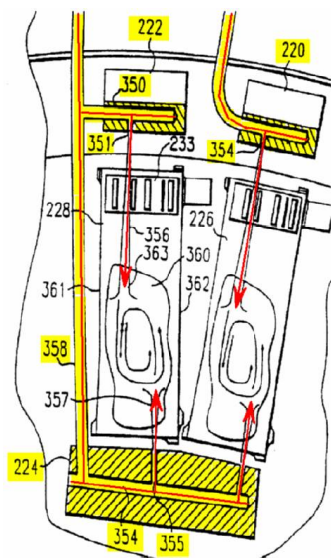
However, the issue of whether the function of the means clause is supplying air or mixing reagents may be academic. It is possible that both are recited functions – namely that Ventana’s proposed function is not wrong, but simply incomplete. It is clear that “for mixing reagents” is a function of the air supply means. It may also be true that “supplying air” is a function. When more than one function is recited, the court should give effect to both. *See Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427-28 (Fed. Cir.1997) (defining the function of the means-plus-function limitation “closure means ... for controlling access” to require that the recited means perform the function of “closing the slot means” in addition to the function of “controlling access.”) Each recited function in a means-plus-function limitation should be given effect. *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1319 (Fed.Cir. 2003) (“[N]either may the function be improperly broadened by ignoring the clear limitations contained in the claim language. The function of a means-plus-function claim must be construed to include the limitations contained in the claim language.”). In either event, the Court

cannot ignore that “mixing reagents” is a recited function, which is exactly what Ventana asks it to do.

#### **D. Structure**

If the Court agrees that “mixing reagents” is a function of the air supply means, then the next step is to identify the corresponding structure that performs this function. Corresponding structure for carrying out the specified function is that which is clearly linked or associated with the claimed function. *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997).

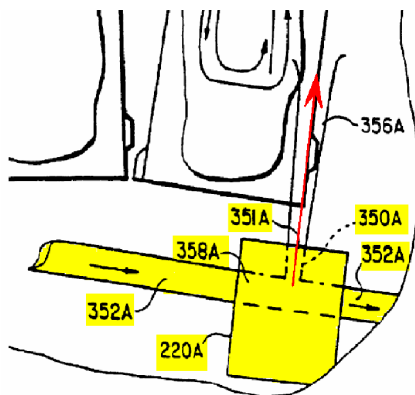
There are two embodiments in the patent with structure associated with the function of mixing reagents. In each there is a channel, a series of fixed blocks, ducts, and channels that are aimed at particular angles. Together they furnish and focus the air flow to the reagent agitation zone, which in turn, mixes the reagents in a vortex fashion. The structures in the written description for the first embodiment that are “clearly linked or associated” with the function of mixing reagents and supplying air are as follows: the “vortex ***mixing*** assembly” of figures 16 and 17, which includes “outer vortex jet block 222” and “inner vortex air jet nozzle block 224”; “pressurized ***air supply*** channel 350 and nozzle 351”; and “channel 35[4]” which “***supplies*** nozzle 355 in block 224 with pressurized ***air***.” (Col. 12, lines 46 – 53.) The “nozzles 351 and 355 have central axes which form angles ‘d’ and ‘e’ from 5 to 15° with the horizontal, ***directing air*** jets 356 and 357 toward the slide surface at the corresponding acute angles.” (Col. 12, lines 53 – 56.) In addition, “pressurized ***air is supplied*** to the nozzle channels 350 and 354 by channel 358.” (Col. 12, lines 58 – 60.) These structures are depicted below.



(Ex A, Figs. 17, 16.) In the alternative embodiments, the structures that are “clearly linked or associated” with the function of mixing reagents and supplying air are as follows:

Each vortex *mixer* 220A has a nozzle channel 350A, including a nozzle orifice 351A, which is *supplied* with pressurized *air* via a supply channel 358A, the nozzle channel 350A preferably intersecting the supply channel at a lower portion thereof. *Pressurized air is supplied* to the supply channel 358A from a [sic] *air supply* conduit 352A ... connected to a pressurized air source ... Each of the vortex *mixers* 220A can be *supplied with pressurized air* via a common supply conduit 352A which connects and *supplies* each of the supply channels 358A of the plurality of *mixers* 220A ...

(Col. 23, lines 30-41, emphasis added). They are depicted below.



(Ex. A, Fig. 32.)

In each of these embodiments, air travels through the channels, the vortex mixers and the nozzles. These items are fixed in locations and aimed such that they produce an air jet that blows on the edges of the reagent puddle and cause the reagents to twirl in circles, without spilling. In other words these are the structures that serve the function of mixing the reagents. Accordingly, they constitute the corresponding structure for claim construction purposes.

However, even if the Court agrees with Ventana that “supplying air” is the only function of the means clause, the corresponding structure is very similar. Again, in determining the corresponding structure for carrying out the specified function, courts require that the specification “clearly link or associate” definite structure with the claimed function. *B. Braun Med.*, 124 F.3d at 1424. The channels, ducts, air mixer blocks and nozzles are all necessary and all linked to and associated with the function of supplying air. Whether the function includes mixing reagents or not, these structures are plainly linked to the function of supplying air.

By contrast, Ventana argues that the corresponding structure is only a nozzle. But without channels or other structures to guide air to it, a nozzle is essentially useless. It is akin to a nozzle on the end of a garden hose. This nozzle alone will not water the lawn. The hose and valves that feed the nozzle are necessary as well. Accordingly, Ventana’s proposed construction is incomplete. It simply does not include all of the associated structure.

In summary, the means-plus-function limitation has mixing reagents as a function. And whether or not supplying air is a function, the corresponding structure includes the channels, vortex air mixers, and nozzle, as detailed above.

**i. “Adjacent”**

DakoCytomation’s Proposed Construction:

***Next to, but not above or underneath.***

The asserted claims of the '901 patent require that the air supply means be positioned "adjacent to" the reagent agitation zone. The plain meaning of the term "adjacent" is "next to". Moreover, "adjacent" does not ordinarily mean above or underneath. This common understanding is consistent with the written description and required by the file history.

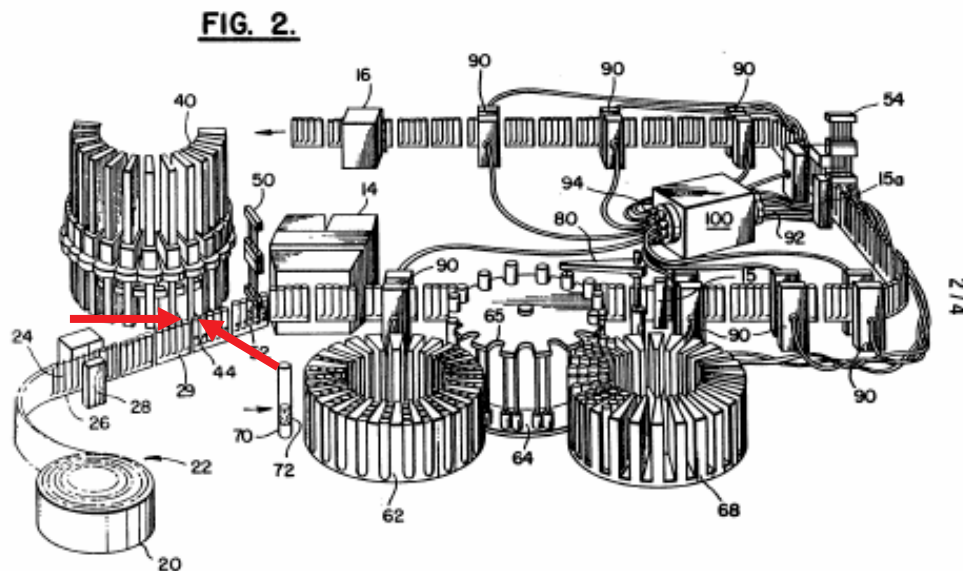
The term "adjacent" is used liberally throughout the patent and file history. Indeed, there are over 100 uses of "adjacent" in the intrinsic record. In each instance, "adjacent" refers to items that are "next to" each other. While sometimes one of the recited adjacent structures is slightly elevated, it is never directly above or beneath the other. Moreover, the written description indicates that the "adjacent" as used in the claims must mean "next to."

Statements in the specification do not typically translate to claim limitations, except when the inventor intends for the claims and the embodiments in the specification to be strictly coextensive. *Phillips*, 415 F.3d at 1323. One good indicator of the inventor's intent is whether a feature is described as part of the invention or simply an embodiment of the invention. *Scimed Life Sys., Inc., v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (limiting the patentee's claims to catheters having coaxial lumens because the patentee characterized the "present invention" as having a coaxial lumen.); *Modine Mfg. Co. v. ITC*, 75 F.3d 1545, 1551 (Fed. Cir. 1996) ("[W]hen the 'preferred embodiment' is described as the invention itself, the claims are not entitled to a broader scope than that embodiment.") This patent makes clear that the "invention" is limited to an instrument wherein "adjacent" structures are "next to, but not above or underneath" one another. In the '901, under the heading "disclosure of the invention," the inventors advised:

In another *aspect of this invention*, the reagent solution is stirred ... by applying at least one gas stream ..., the gas stream having a central axis forming an acute angle with the planar support surface.

(Col. 4, line 47 – 53, emphasis added). To achieve this acute angle, the structure that supplies the air and mixes the reagents cannot be directly above the sample<sup>3</sup>. In fact, the structure must be next to the sample. This indicates that the inventors intended “adjacent” to mean “next to.”

The file history confirms this construction. In fact, during prosecution, the inventors emphasized that “adjacent” does not mean under or underneath. In arguing about the meaning of “a slide position *below* the reagent carousel,” the Ventana inventors reasoned that certain prior art was distinguishable because it disclosed sample carousels that are “*adjacent to* and *not below*” the reagent carousels. The “adjacent” structures are identified below.

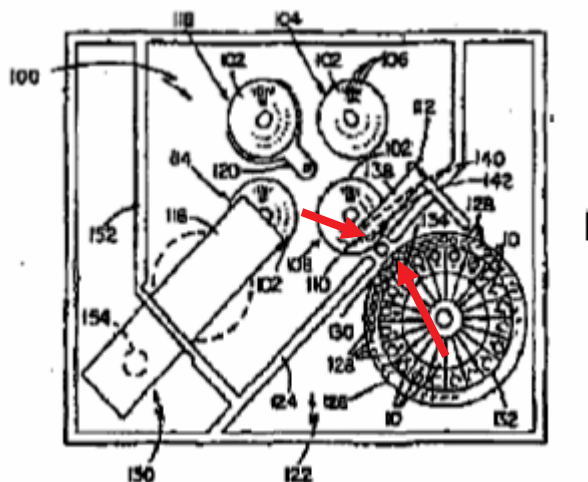


(Ex. B at 14; Ex. C.) In another example, Ventana argued that a prior art reference was distinct because it disclosed a cuvette rotor “that is *adjacent to* [a] reagent table and *not*

<sup>3</sup> An acute angle is less than  $90^\circ$ . If the gas stream were directly above the sample, it would create a  $90^\circ$  angle. Since the angle must be less than that, the gas stream must come from beside, or next to the sample.

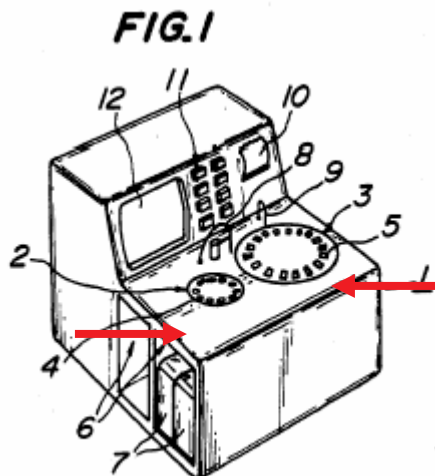


*beneath* the reagent carousel.” Again, the “adjacent” items are depicted below, this time in an overhead view.



(Ex. B at 14; Ex. K.) In still another example, Ventana argued:

[T]he invention of claim 72, et al. includes a sample carousel arranged *beneath* a reagent carousel or when the reagent is dispensed onto a slides [sic] position below the reagent carousel. Neither Sakurda [sic], Rokugawa or Gibbs disclose such an arrangement. In Sakurda [sic], the sample carousel is *adjacent to* the reagent carousel. In Rokugawa, the reagents are located in the carousel while samples are located in trapezoidal containers *adjacent to* the reagent carousel.



(Ex. B at 20; Ex. L.) The “adjacent” items are again identified. The patentee’s explanation of the term “adjacent” applies to its meaning as a claim term. *Southwall*

*Techns., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995) (“[A]rguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent.”)

Thus throughout the intrinsic record, “adjacent” means “next to.” Moreover, the inventors made clear that “adjacent” is different from “below” or “beneath.” By logical extension, and consistent with its plain and ordinary meaning, “adjacent” is also different from “above.” Accordingly, the proper construction of “adjacent” is “next to, but not above or beneath.”

Ventana’s proposed construction of “adjacent” is simply “near.” This is unduly broad. It ignores the plain meaning of the term, is inconsistent with the patent’s written description and ignores express statements in the file history. Accordingly, it should be rejected.

### **III. CONCLUSION**

For the foregoing reasons, DakoCytomation respectfully requests that the Court adopt its proposed claim constructions for the disputed terms. For the Court’s convenience, a separate list of those constructions is attached hereto as Exhibit M.

Dated: October 17, 2005

FISH & RICHARDSON P.C.

By: */s/ Timothy Devlin*

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 17, 2005, I electronically filed **DEFENDANT DAKOCYTOMATION CALIFORNIA INC.'S MARKMAN BRIEF** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on April 13, 2005, I have mailed via Federal Express, the document(s) to the following non-registered participants:

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